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C O N F I D E N T I A L SECTION 01 OF 03 TAIPEI 002143

SIPDIS

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SUBJECT: COUNTERFEIT PHARMA NOT A PRIORITY FOR TAIWAN DOH

REF: 04 TAIPEI 3198

Classified By: AIT Director Douglas Paal, Reason 1.4 (d)

1. (SBU) Summary: Following the March 2004 passage of amendments to Taiwan's Pharmaceutical Law that increased penalties for trafficking in counterfeit pharmaceuticals, Taiwan's Department of Health (DOH) is now beginning to look for ways to address concerns about pharmaceutical piracy and the sale of unlicensed copies of active ingredients in medicines and food supplements. Officials from the DOH and from Taiwan Customs reported an increase in the number of cases of counterfeit medicines discovered and seized in 2004. The National Police and the Coast Guard also reported making seizures. In spite of what appears to be increasing awareness of the need to "do something" about counterfeit drugs, DOH is driven by its concern for consumer protection rather than respect for intellectual property. In addition, Taiwan's system for pharmacy accreditation is weak, DOH has no enforcement or national inspection arm, and sees no need to cooperate with the Taiwan Intellectual Property Office (TIPO) to glean best practices in the fight against counterfeits. End Summary.

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Counterfeit Pharma a Problem, but How Big?
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2. (U) International pharmaceutical manufacturers have long complained that pharmaceutical counterfeiting is a serious problem in Taiwan. An oft-cited 2002 survey by a major international pharmaceutical research manufacturer claimed that approximately 40 percent of Viagra sampled in several hundred pharmacies all over Taiwan was counterfeit or an unlicensed parallel import. One quarter of an expensive heart medication was found in the same survey to be counterfeit. This 2002 survey remains the best estimate of the scale and scope of the problem and seems to be supported by the results of MJIB and National Police raids. Since this survey, manufacturers have estimated that around 25 percent of research-based pharmaceuticals sold in Taiwan are counterfeit or unlicensed. The DOH also uses this figure in discussing the prevalence of unlicensed drugs. The USTR Special 301 report in 2005 listed pharmaceutical piracy as an area of concern for the first time.

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DOH Defines the Problem, but Lacks Power
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3. (U) In response to increasing concern about counterfeit pharmaceuticals, DOH began a pilot project in March 2005 to try to identify which medical products, including pharmaceuticals and non-pharmaceutical supplements, are most popular among by Taiwan consumers. According to DOH Bureau of Pharmaceutical Affairs Chief Wang Hui-po, DOH has contracted an outside research institute to conduct a survey, the results of which should be known by June. DOH then plans to use the results of that survey to target the most popular products for testing to determine the percentage of these products that are counterfeit or contain unlicensed ingredients. DOH sees the problem purely as a consumer safety issue and does not distinguish between fake pharmaceuticals and unlicensed ingredients or additives. This is in contrast to pharmaceutical manufacturers, which tend to view the problem as a lack of protection of their intellectual property that not only hurts their sales and reputations but puts consumers at risk.

4. (U) DOH's efforts to combat counterfeit pharmaceuticals are made more difficult by the fact that it has no statutory enforcement arm, nor does it have any official role in accrediting pharmacies. Instead, DOH relies on county health authorities to conduct ad hoc and sporadic inspections of pharmacies as part of their regular duties and the National Police and Ministry of Justice Investigation Bureau (MJIB) to carry out inspections and raids of night markets or other unlicensed distribution channels. Pharmacies, once licensed, do not have to renew that license and are only subject to biennial accreditation inspections by the county pharmaceutical association.

15. (C) According to DOH statistics, there were five cases of counterfeit pharmaceuticals reported by the county pharmaceutical associations in the last year. DOH itself filed 72 cases in 2004 accusing vendors of selling counterfeit or unlicensed drugs. 27 of these cases involved food products and supplements, 21 involved herbal medicines. The active ingredients of Viagra and Cialis were the most often illegally added to pills or drinks that were then marketed as sexual potency aids.

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Coordination to Combat Counterfeiting
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16. (U) In 2003, DOH established a committee to facilitate the sharing of information about pharmaceutical counterfeiting. The committee includes representatives from the Ministry of Justice (MOJ), Taiwan Customs, the Taiwan Coast Guard, the Ministry of the Interior (which includes the National Police), the International Research Pharmaceutical Manufacturers Association (IRPMA), local pharmaceutical manufacturers associations, and the Taiwan Pharmacists Association, in addition to DOH. The Committee meets biannually and provides agencies the opportunity to share information and best practices, and offers training for enforcement officials on how to recognize counterfeit products.

17. (U) That training appears to be paying some dividends. Enforcement agencies active in the Counterfeit Pharmaceutical Committee (DOH, Customs, the Coast Guard, and the National Police) report a steady increase in the number of cases of counterfeit or unlicensed drugs: 84 cases in 2002, 171 in 2003, and 249 cases in 2004. Taiwan Customs has been most active, filing 23 cases in 2002, 103 in 2003, and 160 in 2004. Taiwan Customs officials tell AIT they believe that the majority of these counterfeit products originate in China and are destined for the Taiwan market. The Ministry of Justice and National Police cooperated on an investigation in the summer of 2004 that led to the seizure of almost a million doses of Viagra, Reductil, and Stilnox with a street value of several million US dollars that were allegedly produced in Guangdong Province and smuggled into Taiwan on fishing boats. (reftel)

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"Protecting IP not DOH's Job"
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18. (SBU) According to Dr. Wang, DOH's primary concern is consumer protection, not the protection of intellectual property. Taiwan's adverse reaction reporting system has not yet reported any case of illness or death brought about by an adverse reaction to a counterfeit pharmaceutical product. For that reason, DOH prefers to focus its attention on specific products that make exaggerated claims or do not meet sanitary production standards. In 2005, DOH is concentrating its efforts on inspecting medicated liquors. Wang noted that MOJ had been making specific efforts to focus on counterfeit drug cases in 2004 and had had some success, offering to pass the ultimate responsibility for combatting counterfeit pharmaceuticals to them. When asked if DOH had ever considered cooperating with TIPO to find ways to successfully combat counterfeit pharmaceuticals, Wang dismissed the idea, noting that the Pharmaceutical Law makes public health concerns paramount, not IP protection and that TIPO didn't have a role to play in protecting public health.

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Comment: DOH Passing the Buck on Pharmaceutical Piracy
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19. (C) Despite their positive spin, it is clear that DOH has no idea of the scale of pharmaceutical counterfeiting in Taiwan, is not making combating piracy a priority, and seems happy to pass the buck to MOJ, the county health authorities or others. The pilot project proudly touted by Dr. Wang as evidence of DOH's commitment to rooting out counterfeiters will not produce a list of potential target products for monitoring before July and appears to be aimed more at unlicensed food additives and supplements. Wang told AIT that recently installed DOH Minister Hou had not yet been briefed on the project, further calling into question the importance DOH places on even this meager effort. The 2004 amendments to the pharmaceutical law were a very positive step in that they substantially increased penalties for manufacture, sale and distribution of counterfeit products, but given the slowness of the judicial process in Taiwan we will not see increases in sentences for infringers until later this year at the earliest. While DOH's commitment to consumer protection is laudable, they are not likely to take a leadership role in efforts to reduce the scale of pharmaceutical counterfeiting in Taiwan's market until there is a public health crisis caused by fake drugs.

PAAL